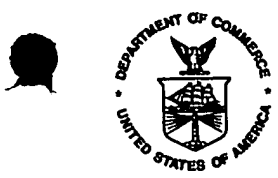


UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/164,862	10/01/98	PRICE	P 023070-08672

020227
MAJESTIC PARSONS SIEBERT & HSUE
SUITE 1100
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4106

HM12/0524

EXAMINER	
SUN HOFFMAN,L	

ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/164,862	Applicant(s) Price
	Examiner First Last	Group Art Unit 1234

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-62* is/are pending in the application.

Of the above, claim(s) *19-37 and 40-46* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-18, 38, 39, and 47-62* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6,11, 14*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

* Raw Seq. Listing Error Report
* Notice to comply with Seq. Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-18 in Paper No. 18 is acknowledged. The traversal is on the ground(s) that it would not pose an undue burden on the Examiner to examine all of Groups I-IV. Upon reconsideration Groups I and III, all drawn to methods of detecting cancer (or its recurrence) comprising the detection of YKL-40 are rejoined. Applicant's arguments concerning the joining of Groups II and IV with Group I are not found persuasive. Applicant has pointed to no errors in the restriction requirement. As to the question of burden of search, the claims of Groups I and II are classified differently, necessitating diffferent searches in the U.S. Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Group IV invloves additional searcing of subject matter relating to bacterial infections. Clearly different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made FINAL.

Claims 1-18, 38-39 and 47-62 are pending for the examination.

Information Disclosure Statement

2. References AT and ABB on the information disclosure statement filed 4/16/99 have not been considered by the examiner. Copies of these two references were not found in the file. Applicant is invited to provide replacement copies for considereation by the examiner.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.R.F. § 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report. Applicant is given the RESPONSE PERIOD OF THIS OFFICE ACTION within which to supply the correction in order to avoid abandonment. EXTENSIONS OF THIS TIME LIMIT MAY BE GRANTED UNDER 37 CFR 1.136(a). Any questions regarding compliance with the sequence rules requirements specifically should be directed to Mark Spencer at 703-308-4212.

Claim Rejections - 35 USC § 112

4. Claims 1-18, 47-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in a recitation of "a adrenal gland cancer." It probably should be "an adrenal gland cancer."

Claim 47 is vague and indefinite in a recitation of "statistically significant difference." It is not clear what kind index applicants are using for the statistic calculation.

Claim 50 is vague and indefinite for using improper Markush group. "And" should be inserted before "a prostate cancer."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1, 9-13, 15-17, 38, 39, 47-50, 52, 56-57, 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Johansen et al.(European J. Cancer, Vol. 31A, No.9, pp. 1437-1442, 1995).

Claims 1, 9, 10, 38, 39, 47-50, 52, 56 are drawn to a method for estimating length of survival of a cancer patient or screening for a cancer or recurrence of cancer, said method comprising:

Obtaining a biologic sample from a cancer patient; measuring a level of YKL-40, wherein in the higher level YKL-40 comparing to the normal level indicating a reduced survival expectancy or the presence of cancer.

Claims 11-13, 15-17, 57, 59-61 are drawn to the different immunoassays for detecting the YKL-40.

Johansen et al teach a method for estimating length of survival of breast cancer patients or screening breast cancer or recurrence of cancer by detecting YKL-40 from blood samples (abstract; page 1438, column 2, 3rd paragraph). The reference also teaches immunoassy methods

such as RIA, ELISA by antisera against YKL-40 (page 1438, column 2, 4th and 5th paragraphs). The reference also teaches a method for using statistical analysis (page 1438, column 2, 7th paragraph). Therefore, the reference anticipates claims 1, 9-13, 15-17, 38, 39, 47-50, 52, 56-57, 59-61.

7. Claim1, 4-10, 11-18, 47-49, 56-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Robbins et al (US Patent No: 5726061, filed 10/8/96, issued 3/10/98).

Claims 4-8 further limit claim 1 in reciting colorectal cancer and Duke's stage A-D colorectal cancer.

Claims 18 and 62 are drawn to a monoclonal antibody.

Robbins et al teach a method for screening for colorectal cancer by measuring levels of HC gp-39 (also called YKL-40), wherein the subtypes of colorectal are inherently included. The reference also teaches the method for monitoring the cancer, wherein the method for estimating the survival is inherently taught(see abstract, column 3, second paragraph). Moreover, Robbins also teaches a method for using immunoassays such as RIA, ELISA, competitive binding assay to detect the HC gp-39 protein in a patient (column 3, lines 30-36). Robbins further teaches a method of using an antibody, prefer a monoclonal antibody (column 4, lines 34-35). Therefore, the reference anticipates the claims.

Claim Rejections - 35 USC § 103

8. Claim 1-18, 47-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen et al over Maggio et al (US Patent No. 4828981, issued on 5/9/89) and Harlow et al

(Antibodies, A laboratory Manual, Cold Spring Harbor Laboratory, 1988, pages 148-212) and Price et al (WO 95/01995, 1/19/95).

Claims 2-3, 51, 53-55 are drawn to different type of cancer.

Claims 10 and 49 are drawn to a biological sample from blood, plasma, serum, synovial fluid etc.

Claim14 and 58 are drawn to a competitive immunoassay.

Johansen et al disclose as set forth in 102(b) rejection. However, Johansen et al differ from the instant invention in failing to disclose other types of cancer, a monoclonal antibody, and different sources of samples. Price et al disclose a method for testing serum and synovial fluid(page 35, lines 5-14). Harlow et al discloses a method for making a monclonal antibody (page 196-212). Maggio et al teach a method of competitive immunoassay.

It would have been *prima facie* obvious for one of the ordinary skill in the art at the time the invention was made to use the method taught by Johansen et al for detecting cancers One of ordinary skill in the art would have been motivated to substitute other cancers such for breast cancer because one of ordinary skill in the art would have recognized the testing the level of YKL-40 would provide the same information as the test in breast cancer as suggested by Johansen et al (see page 1442, column 1).

In addition, it would have been *prima facie* obvious for one of the ordinary skill in the art at the time the invention was made to make a monoclonal antibody. One of ordinary skill in the art would have been motivated to introduce a YKL-40 fragment into an animal with an immunogen and subsequently taking the spleen cell from the animal to make the hybridoma which

secretes a single antibody species to the antigen, because of the teaching by Harlow et al. Therefore, one of ordinary skill in the art would have reasonable expectation of success of making these monoclonal antibodies specific to YKL-40. Moreover, it is obvious to use the same from different places since Price et al disclose tests of YKL-40 in these samples. Finally, it is obvious for one of the skill in the art at the time of the invention to substitute competitive immunoassay as disclose by Maggio et al for RIA or ELISA because it functions in a same manner in providing the detecting of YKL-40 protein.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, Ph.D., who can be reached on (703) -305-3995.

Lin Sun-Hoffman, Ph.D.

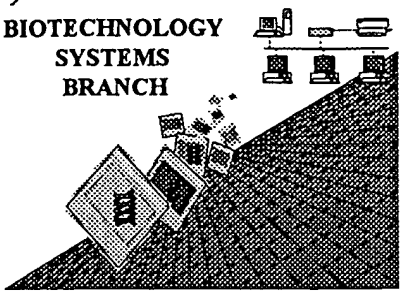
May 22, 2000

NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER

Sue Hoffman

1 of

BIOTECHNOLOGY SYSTEMS BRANCH



RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following CRF diskette:

Application Serial Number: 09/164,862

Art Unit / Team No. : 1642

Date Processed by STIC: 3/15/2000

THE ATTACHED PRINTOUT EXPLAINS THE ERRORS DETECTED.

PLEASE BE SURE TO FORWARD THIS INFORMATION TO THE APPLICANTS BY EITHER:

1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANTS ALONG WITH A NOTICE TO COMPLY or,

2) CALLING APPLICANTS AND FAXING THEM A COPY OF THE PRINTOUT WITH A NOTICE TO COMPLY

THIS WILL INSURE THAT THE NEXT SUBMISSION RECEIVED FROM THEM WILL BE ERROR FREE.

IF YOU HAVE ANY FURTHER QUESTIONS, PLEASE CALL:

MARK SPENCER 703-308-4212

Raw Sequence Listing Error Summary

ERROR DETECTED | SUGGESTED CORRECTION | SERIAL NUMBER: 09/164,862

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1 ____ Wrapped Nucleics
The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".

2 ____ Wrapped Aminos
The amino acid number/text at the end of each line "wrapped " down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".

3 ____ Incorrect Line Length
The rules require that a line not exceed 72 characters in length. This includes spaces.

4 ____ Misaligned Amino Acid Numbering
The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs between the numbering. It is recommended to delete any tabs and use spacing between the numbers.

5 ____ Non-ASCII
This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCii text so that it can be processed.

6 ____ Variable Length
Sequence(s) ____ contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and indicate in the (ix) feature section that some may be missing.

7 ____ PatentIn ver. 2.0 "bug"
A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequence(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence.

8 ____ Skipped Sequences (OLD RULES)
Sequence(s) ____ missing. If intentional, please use the following format for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X:
(i) SEQUENCE CHARACTERISTICS:(Do not insert any headings under "SEQUENCE CHARACTERISTICS")
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X:
This sequence is intentionally skipped

Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).

9 ____ Skipped Sequences (NEW RULES)
Sequence(s) ____ missing. If intentional, please use the following format for each skipped sequence.
<210> sequence id number
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000

10 ____ Use of n's or Xaa's (NEW RULES)
Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.

11 ____ Us of <213>Organism (NEW RULES)
Sequence(s) _____ are missing this mandatory field or its response.

12 ____ Use of <220>Feature (NEW RULES)
Sequence(s) ____ are missing the <220>Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213>ORGANISM is "Artificial" or "Unknown"
Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)

13 ____ PatentIn ver. 2.0 "bug"
Please d not us "C py t Disk" function f PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
Instead, please use "File Manager" or any other means to copy file t floppy disk.

Sun-Hoffman

PAGE: 1

RAW SEQUENCE LISTING
PATENT APPLICATION **US/09/164,862**

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TIME: 15:32:41

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This Raw Listing contains the General Information Section and up to first 5 pages.

Does Not Comply
Corrected Diskette Needed

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Johansen, Julia S
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<140> CURRENT APPLICATION NUMBER: US/09/164,862
<141> CURRENT FILING DATE: 1998-10-01
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<400> SEQUENCE: 4

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VERIFICATION SUMMARY
PATENT APPLICATION US/09/164,862

DATE: 03/17/2000
TIME: 15:32:41

Input Set: I164862.RAW

Line	?	Error/Warning	Original Text
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